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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/307,511	05/07/1999	GUY BOURDON	PBLMD-51494	4934
24201	7590	04/28/2004	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045			EREZO, DARWIN P	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/307,511	<b>Applicant(s)</b> BOURDON, GUY	
	<b>Examiner</b> Darwin P. Erez	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 16, 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of US 4,637,386 to Baum.
4. As to claim 16, the Siemens Servo Ventilator 300 is a breathing aid device comprising: a patient connection (it is inherent for the ventilator to have a connection to the patient; an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3); an expiratory branch in fluid communication with the patient connection and the inspiratory branch; means for controlling expiration in fluid communication with the expiratory branch, the means for controlling expiration including an expiration valve (page 17, number 11);

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means for detecting pressure operatively connected to the inspiratory branch (page 17, number 11); and means for ventilating in fluid communication with inspiratory branch, the means for ventilating including means for supplying a breathable gas through the inspiratory branch at an adjustable pressure (pages 82-83), the means for ventilating further including means for controlling the inspiration valve and the expiration valve (page 17, number 11), the means for ventilating further including pressure control means for comparing a pressure command to a pressure signal provided by the means for detecting pressure and for adjusting the pressure of the means for supplying (page 83); and means for regulating a patient's breathed volume, the means for regulating including means for controlling volume and means for measuring volume (page 83), wherein the means for controlling volume provides the pressure command to the pressure control means, and wherein the means for measuring volume provides a signal indicative of a measured volume of breathed gas to the means for controlling volume (page 84). The manual for the Siemens Servo Ventilator 300 is silent with regards to the inspiration valve being closed during expiration and the expiration valve is closed during inspiration.

Baum teaches a ventilator having an inspiratory branch **2** including an inspiration valve **4**, and an expiratory valve **5**; wherein the inspiration valve is closed during expiration and the expiration valve is closed during inspiration (col. 5, lines 6-61).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the operation of the Siemens Servo Ventilator 300 in order to have the inspiration valve closed during expiration and the expiration

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valve closed during inspiration, as disclosed by Baum, because it allows the user to control high-frequency ventilation (col. 2, lines 3-8) and it also conserves gas by closing the inspiration valve during exhalation (i.e., low gas consumption; col. 3, lines 52-53).

5. As to claim 20, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured volume from the means for measuring volume with the minimum inspired volume per cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and wherein the means for controlling volume maintains the pressure command within the range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

6. As to claim 24, the Siemens Servo Ventilator 300 is a breathing aid device comprising: a patient connection (it is inherent for the ventilator to have a connection to the patient; an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3); an expiratory branch in fluid communication with the patient connection and the inspiratory branch; an expiration device in fluid communication with the expiratory branch, the expiratory branch including an expiration valve (page 17, number 11); a pressure detector operatively connected to the inspiratory branch (page 17, number 11); a source of breathable gas at an adjustable pressure in fluid communication with the inspiratory

branch (page 17, number 3); a valve controller (page 17, number 11; it is inherent for the device to have a controller to control the valves); a pressure controller for comparing a pressure detected by the pressure detector to a pressure command and for adjusting the pressure of the source of breathable gas (page 83); a control unit for providing the pressure command to the pressure controller; and a measuring unit for providing a signal to the control unit indicative of a measured volume of breathable gas detected per breathing cycle to the patient connection (page 84). The manual for the Siemens Servo Ventilator 300 is silent with regards to the valve controller closing the inspiration valve during expiration and closing expiration valve during inspiration.

Baum teaches a ventilator having an inspiratory branch **2** including an inspiration valve **4**, and an expiratory valve **5**; wherein the inspiration valve is closed during expiration and the expiration valve is closed during inspiration (col. 5, lines 6-61).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the operation of the Siemens Servo Ventilator 300 in order to have the inspiration valve closed during expiration and the expiration valve closed during inspiration, as disclosed by Baum, because it allows the user to control high-frequency ventilation (col. 2, lines 3-8) and it also conserves gas by closing the inspiration valve during exhalation (i.e., low gas consumption; col. 3, lines 52-53).

7. As to claim 25, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured

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volume from the means for measuring volume with the minimum inspired volume per cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and wherein the means for controlling volume maintains the pressure command within the range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

8. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of Baum, and in further view of US 5,353,788 to Miles.

The non-patent literature fails to specifically teach the patient connection comprising a facial mask or a nasal mask. Miles teaches that it is known in the art to use a patient connection means comprising a nasal mask **26**, which is also facial mask. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a facial mask or a nasal mask since it is well known in the art to use a nasal mask or a facial mask to connect a patient to a ventilator.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of BAum, and in further view of US 4,941,469 to Adaham.

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10. The non-patent literature fails to teach an adjustable speed motor-turbine set.

Adaham teaches the use of an adjustable motor-turbine set in a ventilator. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the adjustable motor-turbine set of Adaham in the Siemens Servo Ventilator in order to provide air flow to the ventilator.

11. Claims 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of US 4,336,590 to Jacq et al. and in further view of 6,085,747 to Axe et al.

12. As to claim 21, the Siemens Servo Ventilator 300 is a breathing aid device comprising: a patient connection (it is inherent for the ventilator to have a connection to the patient; an inspiratory branch in fluid communication with the patient connection, the inspiratory branch including an inspiration valve (page 17, number 3); an expiratory branch in fluid communication with the patient connection and the inspiratory branch; an expiration device in fluid communication with the expiratory branch, the expiratory branch including an expiration valve (page 17, number 11); a pressure detector operatively connected to the inspiratory branch (page 17, number 11); a ventilation unit in fluid communication with the inspiratory branch, the ventilation unit including a source of breathable gas at an adjustable pressure (pages 82-83), the ventilation unit further including a valve controller for opening and closing the inspiration valve and the expiration valve (page 17, number 11), wherein the inspiration valve is closed during



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expiration and the expiration valve is closed during inspiration, the ventilation unit further including a pressure controller for comparing a pressure detected by the pressure detector to a pressure command and for adjusting the pressure of the source of breathable gas (page 83); and a regulator for regulating a patient's breathed volume, the regulator including a control unit and a measuring unit, wherein the control unit provides the pressure command to the ventilation unit , and wherein the measuring unit provides a signal indicative of a measured volume of breathed gas to the control unit (page 84). The manual for the Siemens Servo Ventilator 300 is silent with regards to the location of the pressure detector.

Jacq teaches a device for providing gas to a patient comprising a mask having a pressure detector (col. 1, lines 46).

Axe also teaches a ventilator having a pressure sensor disposed on a mask (col. 16, line 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to put the pressure detector on the patient connection because it is well known in the art, as taught by Jacq and Axe, to have a pressure detector disposed in a patient connection to monitor the pressure.

13. As to claim 23, the Siemens Servo Ventilator 300 has a means for controlling volume including an input for a minimum inspired volume per cycle, an input for a minimum inspiratory pressure command, and an input for a maximum inspiratory pressure command, wherein the means for controlling volume compares the measured volume from the means for measuring volume with the minimum inspired volume per

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cycle and adjusts the pressure command in the direction tending to bring the signal from the means for measuring volume toward the minimum inspired volume per cycle, and wherein the means for controlling volume maintains the pressure command within the range of the minimum inspiratory pressure command and the maximum inspiratory pressure command (see page 84).

14. Claims 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Siemens Servo Ventilator 300, as disclosed in the non patent literature, Operating Manual for Siemens Servo Ventilator 300, in view of Jacq/Axe, and in further view of US 4,941,469 to Adaham.

15. The non-patent literature fails to teach an adjustable speed motor-turbine set. Adaham teaches the use of an adjustable motor-turbine set in a ventilator. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the adjustable motor-turbine set of Adaham in the Siemens Servo Ventilator in order to provide air flow to the ventilator.

### ***Response to Arguments***

16. Applicant's arguments with respect to claims 16-25 have been considered but are moot in view of the new ground(s) of rejection.

It should be noted that the non patent literature, Operating Manual for Siemens Servo Ventilator 300 and US 4,637,386 to Baum are analogous art because both are in

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the same field of endeavor as the applicant, i.e., both art are directed towards a ventilator for providing breathable air to a patient.

With regards to the Miles and Adahan references, it should be noted that motivations to combine references does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. (see MPEP 2144). A nasal mask or face mask is a well known patient connection means. An adjustable gas source is also well known in the respiratory art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703)308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

dpe

  
GLENN K. DAWSON  
PRIMARY EXAMINER